Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	John W. Darrah	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 1646	DATE	9/12/2002
CASE TITLE	KNOLL PHARMACEUTICAL COMPANY, INC. vs. TEVA PHARMACEUTICALS		

MOTION: [In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Status hearing held and continued to 10/2/02 at 9:00 a.m. Enter Memorandum Opinion And Order. Teva's motion for summary judgment of patent invalidity is granted [[48-1]. Teva's motion for summary judgment of non-infringement [108-1] and plaintiffs' motion for summary judgment of infringement [91-1] are denied as moot.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.		SEP 13 2002 date docketed	186
	Notices mailed by judge's staff.			
	Notified counsel by telephone.			
✓	Docketing to mail notices.	U.S. DISTRICT COURT 02 SEP 12 PM 6:00 FILED-EASTERN	docketing deputy initials	
	Mail AO 450 form.		date mailed notice	
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LG	courtroom deputy's initials	Date/time received in central Clerk's Office	mailing deputy initials	

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

KNOLL PHARMACEUTICAL COMPANY, INC.; and JOHN AND LOIS ARNOLD FAMILY LIMITED LIABILITY PARTNERSHIP,	)	
Plaintiffs,	)	Case No. 01 C 1646
v.	)	The Honorable John W. Darrah
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs, Knoll Pharmaceutical Company, Inc. and the John and Lois Arnold Family Limited Liability Partnership (collectively "Plaintiffs"), filed a complaint against Defendant, Teva Pharmaceuticals USA, Inc. ("Teva"), alleging infringement of United States Patent Number 4,587,252 ("the '252 patent"). Teva has filed, pursuant to Federal Rule of Civil Procedure 56, motions for summary judgment of patent invalidity and non-infringement. Plaintiffs have filed a motion for summary judgment of patent infringement. For the reasons that follow, Teva's motion for summary judgment of patent invalidity is granted. Teva's motion for summary judgment of non-infringement and Plaintiffs' motion for summary judgment of patent infringement are denied as moot.

LEGAL STANDARD

Summary judgment is appropriate when there remains no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Cincinnati Ins. Co.*

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v. Flanders Elec. Motor Serv., Inc., 40 F.3d 146, 150 (7th Cir. 1994). "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses . . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Thus, although the moving party on a motion for summary judgment is responsible for demonstrating to the court why there is no genuine issue of material fact, the non-moving party must go beyond the face of the pleadings, affidavits, depositions, answers to interrogatories, and admissions on file to demonstrate, through specific evidence, that there remains a genuine issue of material fact and show that a rational jury could return a verdict in the non-moving party's favor. *Celotex*, 477 U.S. at 322-27; *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254-56 (1986); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Waldridge v. American Hoechst Corp.*, 24 F.3d 918, 923 (7th Cir. 1994).

Disputed facts are material when they might affect the outcome of the suit. *First Ind. Bank v. Baker*, 957 F.2d 506, 507-08 (7th Cir. 1992). When reviewing a motion for summary judgment, a court must view all inferences to be drawn from the facts in the light most favorable to the opposing party. *Anderson*, 477 U.S. at 247-48; *Popovits v. Circuit City Stores, Inc.*, 185 F.3d 726, 731 (7th Cir. 1999). However, a metaphysical doubt will not suffice. *Matsushita*, 475 U.S. at 586. If the evidence is merely colorable or is not significantly probative or is no more than a scintilla, summary judgment may be granted. *Anderson*, 477 U.S. at 249-50.

BACKGROUND

The undisputed facts taken from the parties' Local Rule 56.1(a) & (b) statements of material facts (referred to herein as "Pl.'s 56.1" and "Def.'s 56.1") and exhibits are as follows.

The John and Lois Arnold Family Limited Liability Partnership ("the Arnold Partnership") is a limited liability partnership having a place of business located in Scottsdale, Arizona. (Def.'s

56.1 ¶ 2.) Teva is a corporation organized and operating under the laws of Delaware, with its principal place of business in North Wales, Pennsylvania. (Def.'s 56.1 ¶ 3.)

United States Patent History

On December 18, 1984, John D. Arnold ("Dr. Arnold") filed with the United States Patent and Trademark Office ("PTO") the application which resulted in the '252 patent. (Def.'s 56.1 ¶ 5; Pl.'s 56.1 ¶ 2.) The application claimed that the combination of hydrocodone and ibuprofen in specific doses and ratios produced a greater analgesic effect than that obtained by using either pain reliever alone. (Pl.'s 56.1 ¶ 2.)

Hydrocodone is a narcotic analgesic. (Def.'s 56.1 ¶ 10.) Hydrocodone bitartrate is a pharmaceutically acceptable salt of hydrocodone. (Def.'s 56.1 ¶ 11.) In 1984, Codone was a trade name for hydrocodone bitartrate. (Def.'s 56.1 ¶ 12.) Ibuprofen is a non-narcotic analgesic. (Def.'s 56.1 ¶ 13.) Ibuprofen aluminum salt and ibuprofen sodium salt are pharmaceutically acceptable salts of ibuprofen. (Def.'s 56.1 ¶ 14.)

In 1985, the United States patent examiner ("the examiner") rejected claims 1 through 6 of Dr. Arnold's United States patent application as being obvious over a one paragraph 1980 abstract of a study conducted by Dr. Stephen A. Cooper of a codeine-ibuprofen combination. (Def.'s 56.1 ¶ 16; Pl.'s 56.1 ¶ 4.) Following that rejection, Dr. Arnold sought reconsideration in light of Dr. Cooper's findings that the analgesic effectiveness of the codeine-ibuprofen combination was not "statistically superior to ibuprofen alone". (Pl.'s 56.1 ¶ 4.) Dr. Arnold argued that the Cooper study taught away from the idea of combining ibuprofen with any other opioid. (Pl.'s 56.1 ¶ 4.)

The '252 patent, entitled "Hydrocodone/Ibuprofen Pharmaceutical Compositions and Method" was issued on May 6, 1986, to Dr. Arnold. (Def.'s 56.1 ¶ 4.) The '252 patent claims the

"date of invention" as December 18, 1984. (Def.'s 56.1 ¶ 6.) The Arnold Partnership is the current owner of the '252 patent. (Def.'s 56.1 ¶ 7.) In May 1988, Knoll obtained an exclusive license to the '252 patent from Dr. Arnold. (Def.'s 56.1 ¶ 8.) Since that time, Knoll has been the exclusive licensee of the '252 patent. (Def.'s 56.1 ¶ 8.)

Dr. Arnold did not disclose another Cooper article in its entirety to the PTO before issuance of the '252 patent. (Def.'s 56.1 ¶ 20.) According to that Cooper article, "[t]he results of this study strongly suggest that ibuprofen 400 mg in combination with codeine 60 mg is an excellent analgesic and deserves more extensive testing in a variety of pain models." (Def.'s 56.1 Ex. 9, Stephen A. Cooper, Jerome Engel, Marvin Ladov, Harry Precheur, Arnold Rosenheck, & David Rauch, *Analgesic Efficacy of an Ibuprofen-Codeine Combination*, 2 Pharmacotherapy 162, 167 (1982)).

Nor did Dr. Arnold disclose to the examiner a previously filed European patent application. The Upjohn Company ("Upjohn") filed this application ("the Upjohn Application"), entitled "Analgesic process and composition", on June 25, 1982, with the European Patent Office ("EPO"). (Def.'s 56.1 ¶ 24.) This application was published by the EPO on January 5, 1983, more than a year before the filing of Dr. Arnold's application with the PTO. (Def.'s 56.1 ¶¶ 24, 25.) The Upjohn Application disclosed that a narcotic analgesic, such as hydrocodone, among others, could be combined with ibuprofen or its salt or ester[1] to act synergistically in the management of moderate to severe pain. (Def.'s 56.1 ¶¶ 26, 27.) The Upjohn Application also disclosed that ibuprofen or its salt may be combined with morphine sulfate, a known narcotic analgesic, and that an "equi-analgesic" dose of hydrocodone may be substituted for morphine sulfate. (Def.'s 56.1 ¶ 30.) The

[1]Esters are a class of compounds that are usually formed by the reaction between an acid and an alcohol with the elimination of water. *See Webster's Third International Dictionary* 778 (3d ed. 1986).

Upjohn Application did not define the term "equi-analgesic". (Pls.' 56.1 ¶ 17.)

Upjohn later abandoned all of its claims based on ibuprofen-opioid combinations and received a European patent based upon flurbiprofen-opioid combinations. (Pls.' 56.1 ¶ 11.)

The examples in the Upjohn Application disclose the use of ibuprofen (or its salt form) in amounts ranging from 50 to 350 mg, in combination with hydrocodone (or its salt form) in amounts ranging from 1 to 49 mg. (Def.'s 56.1 ¶ 31.) Examples 1 to 3 of the Upjohn Application teach that 50 mg of ibuprofen can be combined with 15 mg of morphine sulfate. (Def.'s 56.1 ¶ 32.)

A composition made up of 0.6 to 2 mg of hydrocodone and 50 mg of ibuprofen contains approximately one part by weight hydrocodone and 25 to 83 parts by weight ibuprofen. (Def.'s 56.1 ¶ 34.) This ratio (1:25-83) disclosed in the Upjohn Application overlaps the ratio listed in Claims 3 and 4 of the '252 patent (1:20-80 hydrocodone to ibuprofen). (Def.'s 56.1 ¶ 34.) The Upjohn Application also discloses a composition made up of 1 to 3 mg of hydrocodone bitartrate and 50 mg of ibuprofen which contains approximately one part by weight hydrocodone bitartrate and 17 to 50 parts ibuprofen. (Def.'s 56.1 ¶ 35.) This ratio (1: 17-50) overlaps the ratio listed in Claims 3 and 4 of the '252 patent (1:20-80 hydrocodone to ibuprofen). (Def.'s 56.1 ¶ 35.)

Example 5 of the Upjohn Application teaches that 350 mg of ibuprofen sodium salt, a pharmaceutically acceptable salt of ibuprofen, combined with a half-grain of morphine sulfate, can be injected intravenously to effectively reduce pain. (Def.'s 56.1 ¶ 36.) In 1984, a person of ordinary skill in the art would have known that a half-grain of morphine sulfate is equal to approximately 32 mg of morphine sulfate. (Def.'s 56.1 ¶ 37.) In 1984, a person of ordinary skill in the art would also have known that approximately 10 to 29 mg of hydrocodone (or 16 to 49 mg of hydrocodone bitartrate) administered intravenously is equi-analgesic to 32 mg of morphine sulfate administered

intravenously. (Def.'s 56.1 ¶ 38.) Thus, Example 12 of the Upjohn Application discloses that 350 mg of ibuprofen sodium salt combined with either 10 to 29 mg of hydrocodone (or 16 to 49 mg hydrocodone bitartrate) can be used effectively to treat pain. (Def.'s 56.1 ¶ 39.)

A composition containing 350 mg of ibuprofen sodium salt combined with 10 to 29 mg of hydrocodone contains 1 part hydrocodone and 12 to 35 parts ibuprofen sodium salt. (Def.'s 56.1 ¶ 40.) This ratio (1:12-35) overlaps the ratio (1:20-80) in claims 3 and 4 of the '252 patent. (Def.'s 56.1 ¶ 40.) A composition containing 350 mg of ibuprofen sodium salt combined with 16 to 49 mg hydrocodone bitartrate results in a ratio of 1 part to 7 to 22 parts ibuprofen sodium salt. (Def.'s 56.1 ¶ 41.) This ratio (1:7-22) overlaps with the ratio (1:20-80) in claims 3 and 4 of the '252 patent. (Def.'s 56.1 ¶ 41.) Thus, the Upjohn Application discloses a combination of 350 mg of ibuprofen sodium salt and approximately 10 to 29 mg of hydrocodone administered intravenously, which overlaps the ranges of claims 5 and 6 of the '252 patent ("about 5-10 mg" of hydrocodone and "about 200-400 mg" of ibuprofen salt). (Def.'s 56.1 ¶ 42.)

The Upjohn Application teaches lowering the dosage amount of the narcotic analgesic while maintaining the amount of ibuprofen. (Def.'s 56.1 ¶ 43.) The Upjohn Application further teaches that the narcotic analgesic can be lowered to half the original dose and then to a quarter of the original dose. (Def.'s 56.1 ¶ 44.) Therefore, the Upjohn Application discloses a combination of 5 to 14 mg of hydrocodone (or 8 to 24 mg of hydrocodone bitartrate) combined with 250 mg of ibuprofen sodium salt, which also falls within the claimed ranges of claims 5 and 6 ("about 5 to 10 mg" of hydrocodone and "about 200 to 400 mg" of ibuprofen salt). (Def.'s 56.1 ¶ 45.)

The Upjohn Application further teaches a dosage amount of 15 mg of morphine sulfate and 50 mg of ibuprofen administered "four times a day". (Def.'s 56.1 ¶ 46.) This daily dosage amounts

to 60 mg (15 mg, 4 times per day) of ibuprofen. (Def.'s 56.1 ¶ 46.) Therefore, the Upjohn Application teaches that 5 to 10 mg of hydrocodone bitartrate combined with 200 mg of ibuprofen is an effective dosage amount. (Def.'s 56.1 ¶ 48.) These amounts also overlap with the amounts specified in claims 5 and 6 of the '252 patent ("about 5 to 10 mg" of hydrocodone and "about 200 to 400 mg" of ibuprofen salt). (Def.'s 56.1 ¶ 48.)

Example 4 of the Upjohn Application teaches the administration of a tablespoon dose (15 ml) wherein each teaspoon (5 ml) contains 100 mg of ibuprofen aluminum salt. (Def.'s 56.1 ¶ 49.) Because a tablespoon consists of 3 teaspoons, the Upjohn Application's tablespoon dosage amount contains 300 mg of ibuprofen aluminum salt. (Def.'s 56.1 ¶ 50.) Therefore, the Upjohn Application discloses that 300 mg of ibuprofen aluminum salt (a pharmaceutically acceptable salt of ibuprofen) combined with a quarter grain of morphine sulfate can be administered intramuscularly to reduce pain. (Def.'s 56.1 ¶ 51.) In 1984, a person of ordinary skill in the art would have known that a quarter grain of morphine sulfate is equal to approximately 16 mg of morphine sulfate. (Def.'s 56.1 ¶ 52.)[2]

Dr. Arnold also failed to disclose the product Vicodin to the PTO before the issuance of the '252 patent. (Def.'s 56.1 ¶ 62.) Vicodin is an analgesic combination comprising of 5 mg of hydrocodone and 500 mg of acetaminophen. (Def.'s 56.1 ¶ 57.) Vicodin was approved for use and marketed as early as 1980. (Def.'s 56.1 ¶ 58.) Vicodin was used and sold more than one year before Dr. Arnold filed the '252 patent application with the PTO. (Def.'s 56.1 ¶ 59.) The combination of

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[2]Example 4 of the Upjohn Application contains an obvious typographical error. (Def.'s 56.1 ¶ 49.) Example 4 incorrectly refers to a "*1/4 gram* of morphine sulfate given [intramuscularly] four times a day." (Def.'s 56.1 ¶ 49.) Example 4 should refer to a *one-quarter grain* of morphine sulfate. (Def.'s 56.1 ¶ 49.)

hydrocodone and acetaminophen in Vicodin was published more than one year before Dr. Arnold filed the '252 patent application with the PTO. (Def.'s 56.1 ¶ 60.) Both Vicodin and the claimed invention combine hydrocodone with a non-narcotic analgesic. (Def.'s 56.1 ¶ 61.)

In 1981, Dr. William Beaver published an article in which he documented that a greater analgesic effect can be achieved by combining a centrally acting narcotic analgesic, such as hydrocodone, with a peripherally acting non-narcotic analgesic, such as aspirin or acetaminophen. (Def.'s 56.1 ¶ 63.) In 1983, Dr. Beaver discussed the rationale for existing combinations, including the combination of hydrocodone and acetaminophen found in Vicodin, and reported that ibuprofen shares aspirin's mechanism of action and "can be used to advantage in combination with oral opioids." (Def.'s 56.1 ¶ 64.) In a paper published on September 10, 1984, in the *American Journal of Medicine*, Dr. Beaver suggested the substitution of ibuprofen for the acetaminophen in the Vicodin product. (Def.'s 56.1 ¶ 65.) Dr. Beaver's article did not disclose what opioid should be combined with what non-steroidal anti-inflammatory drug ("NSAID") and in what specific ratios and dosage amounts to achieve an additive effect. (Pls.' 56.1 ¶ 58.) Dr. Arnold never disclosed Dr. Beaver's work to the PTO before issuance of the '252 patent. (Def.'s 56.1 ¶ 72.)

In 1984, known combinations of narcotic and non-narcotic analgesics included: hydrocodone-ibuprofen (disclosed in the Upjohn Application), hydrocodone-acetaminophen (sold under the trade name Vicodin, disclosed in the Beaver article), codeine-ibuprofen (disclosed in the Cooper article), and methadone-ibuprofen (disclosed in Theresa Ferrer-Brechner and Patricia Ganz, *Combination Therapy with Ibuprofen and Methadone for Chronic Cancer Pain*; Am. J. Med. 78 (1984)). (Def.'s 56.1 ¶ 66.) Therefore, in 1984, the enhanced pain-reducing effect of combining narcotic and non-narcotic analgesics was known. (Def.'s 56.1 ¶ 67.) In 1984, a person of ordinary skill in the art of

pain management would have also known that ibuprofen was interchangeable with acetaminophen and that it could be substituted for the acetaminophen in the known hydrocodone combination, Vicodin, and that 500 mg of acetaminophen is equi-analgesic to 200 mg of ibuprofen. (Def.'s 56.1 ¶¶ 68, 69.)

European Patent History

On December 11, 1985, while the '252 patent application was pending before the PTO, Dr. Arnold filed an application for a counterpart European patent ("the European Application"). (Def.'s 56.1 ¶ 73.) The claims of the European Application are identical to the claims of the '252 patent. (Def.'s 56.1 ¶ 74.) In its prosecution of the European Application, the EPO identified the Upjohn Application as relevant prior art and assigned it to the prior art category "X", which means the reference is "particularly relevant if taken alone". (Def.'s 56.1 ¶ 75.) The EPO indicated that the Upjohn Application was relevant to all six claims of the European Application. (Def.'s 56.1 ¶ 75.)

The EPO rejected all six claims of the European Application. (Def.'s 56.1 ¶ 76.) The EPO rejected claims 1 and 2 of the European Application as no longer novel over the Upjohn Application because the Upjohn Application taught "that a narcotic analgesic such as hydrocodone acts synergically with ibuprofen in the management of severe to moderate pain." (Def.'s 56.1 Ex. 14 at 40.)

The EPO first rejected claims 3 through 6 of the European Application as lacking "the necessary inventive step" over the Upjohn Application because the EPO found that the quantities of hydrocodone and ibuprofen disclosed in those claims, the quantities necessary to achieve the greater analgesic effect, were discoverable from the Upjohn Application. (Def.'s 56.1 ¶ 78.) In response to the EPO's rejection, Dr. Arnold amended his European Application and abandoned

claims 1 and 2. (Def.'s 56.1 ¶ 79.)

The EPO then rejected all of the claims of the amended European Application as lacking "the necessary inventive step" over the Upjohn Application. (Def.'s 56.1 ¶ 80.) Specifically, the EPO found that the Upjohn Application's reference to hydrocodone was an "indisputably . . . acceptable example of realization of the invention." (Def.'s 56.1 ¶ 80.) By a decision dated August 10, 1990, the EPO rejected the European Application for the invention claimed in the '252 patent, finding that the combination claimed in the European Application did not have an unexpected pain-reducing effect over the teachings in the Upjohn Application and that the specific compositions of hydrocodone and ibuprofen disclosed in the European Application fell directly within the composition disclosed by the Upjohn Application. (Def.'s 56.1 ¶ 81.)

Dr. Arnold appealed the EPO's decision and presented new experimental data to the EPO. (Def.'s 56.1 ¶ 82.) After considering the new experimental data which Dr. Arnold submitted, the EPO concluded that the claims of the European Application were not novel over the Upjohn Application and refused the application. (Def.'s 56.1 ¶ 81.)

The State of the Art in 1984

Since at least the 1970s, there have been three ways of measuring analgesic effectiveness: (1) duration of action (how long the analgesic effect lasted); (2) time to peak effect (time when pain relief is greatest); and (3) total effect (a composite measure of pain relief). (Pls.' 56.1 ¶ 12.) In determining "equi-analgesic" doses for purposes of treating acute pain, the "peak effect" measurement is important, while the "duration of action" measurement is the primary focus in treating chronic pain. (Pls.' 56.1 ¶ 13.) The determination of the "equi-analgesic" dose depends on which route of administration is used: oral, intravenous ("IV"), subcutaneous ("SC"), or

intramuscular ("IM"). (Pls.' 56.1 ¶ 14.)

Oral administration of an opioid results in a lower "peak effect" than the IV route because the drug is not delivered as rapidly to the bloodstream. (Pls.' 56.1 ¶ 14.) By contrast, IV delivery is instantaneous; whereas, delivery via the IM and SC routes is slower since the drug must first be absorbed from the muscle tissue or subcutaneous fat into the blood. (Pls.' 56.1 ¶ 15.) As a result, the "peak effect", "duration", and "total effect" measurements generally vary across the routes of administration for each opioid. (Pls.' 56.1 ¶ 15.)

Different opioids also vary widely in the nature and quality of their analgesic effectiveness, particularly through different routes of administration. (Pls.' 56.1 ¶ 16.) Oral morphine is much less effective than IM morphine because most of the oral morphine is rendered inactive in the course of being absorbed by the digestive tract. (Pls.' 56.1 ¶ 16.) As a result, only ten to forty percent of orally-administered morphine is otherwise available for analgesic effect. (Pls.' 56.1 ¶ 16.) On the other hand, when morphine is administered intravenously, intramuscularly, or subcutaneously, it typically becomes 100 percent available for analgesic effect. (Pls.' 56.1 ¶ 16.) By contrast, hydrocodone is usually administered orally because its effectiveness is not compromised as it is absorbed through the digestive tract. (Pls.' 56.1 ¶ 16.) The Upjohn Application does not explain how any of the above factors should be taken into account in determining "equi-analgesic" doses. (Pls.' 56.1 ¶ 17.)

The prior art included tables that identified the standard doses of various opioids. (Pls.' 56.1 ¶ 18.) The tables were intended to provide guideline doses for physicians who were using opioids in treating the pain of their patients. (Pls.' 56.1 ¶ 19.) Such guidelines recognized that the physician must consider many variables when changing either the drug or the route of administration. (Pls.'

56.1 ¶ 19.) The tables suggested guideline doses that were the starting points from which the physicians worked to determine the equi-analgesic amount of alternative drugs in each individual case. (Pls.' 56.1 ¶ 19.)

In 1984, hydrocodone was used as an anti-tussive (cough suppressant). (Pls.' 56.1 ¶ 20.) The twenty-eighth edition of *Martindale: The Extra Pharmacopoeia*, which was published in 1982, does not state that the different doses of hydrocodone for oral and SC administration are "equi-analgesic". (Pls.' 56.1 ¶ 28.)

Teva has presented expert evidence that in 1984 a person of ordinary skill in the art of pain management would have known that: (1) ibuprofen could be combined with hydrocodone to create a combination analgesic that achieves a greater analgesic effect than either of the two drugs alone, (Def.'s 56.1 ¶ 71); (2) approximately 5 to 14 mg hydrocodone (or 8 to 24 mg of hydrocodone bitartrate) administered intramuscularly is equi-analgesic to 16 mg of morphine sulfate administered intramuscularly, (Def.'s 56.1 ¶ 53); (3) 5 to 10 mg of hydrocodone bitartrate administered orally is equi-analgesic to 60 mg morphine sulfate administered orally, (Def.'s 56.1 ¶ 47); and (4) approximately 0.6 to 2 mg of hydrocodone (or 1 to 3 mg of hydrocodone bitartrate) taken orally is equi-analgesic to 15 mg of morphine sulfate taken orally. (Def.'s 56.1 ¶ 33.) Plaintiffs' expert contests each of these assertions. (*See* Pls.' 56.1 Ex. 1.)

Events Leading Up to Suit

In 1997, the Food and Drug Administration ("FDA") approved Knoll's New Drug Application for Vicoprofen based on clinical data showing that Vicoprofen satisfied the FDA's policy requiring clinical evidence that an analgesic combination was more effective than each of its components alone. (Pls.' 56.1 ¶ 63.) Since its market introduction in 1997, Vicoprofen has averaged

more than $70,000,000 in annual prescription sales, with the prescription sales of the last year exceeding $100,000,000 in a heavily-genericized market. (Pls.' 56.1 ¶ 76.)

A study at the University of Connecticut evaluated the effects of Vicoprofen on individuals who had incurred muscle damage as a result of exercise injuries. (Pls.' 56.1 ¶ 74.) Investigators administered Vicoprofen to individuals who had suffered muscle damage through exercise within twenty-four hours of the muscle damage. (Pls.' 56.1 ¶ 74.) Investigators discovered that Vicoprofen enhanced the performance of damaged muscles in the first forty-eight hours following injury, suggesting that Vicoprofen can play a role in reducing the effects of muscle damage caused by exercise. (Pls.' 56.1 ¶ 75.)

Teva has submitted an Abbreviated New Drug Application ("ANDA") to the FDA for approval of hydrocodone bitartrate and ibuprofen tablets, 7.5 mg/200 mg. (Pls.' 56.1 ¶ 1.) The ANDA seeks approval to manufacture or sell for use in treating pain in a mammal a pharmaceutical composition which comprises of hydrocodone (or a pharmaceutically acceptable acid addition salt thereof) and ibuprofen (or a pharmaceutically acceptable acid addition salt thereof). (Pls.' 56.1 ¶ 2.) The ANDA seeks approval to manufacture or sell a pharmaceutical composition comprising of a pharmaceutically acceptable carrier and an analgesically effective amount of: (1) one part by weight of an analgesic agent selected from the group consisting of hydrocodone and pharmaceutically acceptable acid addition salts thereof and (2) about 20 to 80 parts by weight of ibuprofen or a pharmaceutically acceptable acid salt thereof. (Pls.' 56.1 ¶ 5.) Plaintiffs then filed a single-count complaint, alleging that Teva's ANDA infringed the '252 patent and seeking damages and injunctive relief.

DISCUSSION

Claim Construction

Claim construction is a question of law. *Kopykake Enters., Inc. v. Lucks Co.*, 264 F.3d 1377, 1381 (Fed. Cir. 2001). Claim construction "is the process of giving proper meaning to the claim language", which defines the scope of the claim. *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023 (Fed. Cir. 1997). "[A]ll terms in a patent claim are to be given their plain, ordinary and accustomed meaning to one of ordinary skill in the relevant art." *Rexnord Corp.* v. *Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). Absent compelling circumstances, "a court will give a claim term the full range of its ordinary meaning as understood by an artisan of ordinary skill." *Rexnord*, 274 F.3d at 1342. Claim terms will be construed in a way that is consistent with their appearance in other claims of the same patent or other parts of the same claim. *Rexnord*, 274 F.3d at 1342.

The claim language is the focus of determining the meaning of disputed claim terms. *Abtox*, 122 F.3d at 1023. However, courts will consider intrinsic evidence, the claims, the specification, and the prosecution history. *Kopykake Enters.*, 264 F.3d at 1381. If the meaning of the disputed terms are still ambiguous after consideration of intrinsic evidence, courts will consider extrinsic evidence. *Kopykake Enters.*, 264 F.3d at 1381. Although a dictionary is considered extrinsic evidence, "[j]udges are free to consult such resources at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996).

Once the court has ascertained the meaning to one of ordinary skill in the art of the disputed

term, the court will examine the written description and drawings to be certain that the patentee's use of the term is consistent with the meaning determined by the court. *Rexnord*, 274 F.3d at 1342. A claim construction that excludes the preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." *Rexnord*, 274 F.3d at 1342 (quoting *Vitronics*, 90 F.3d at 1583). The drawings and written description are examined "to determine whether the patentee has disclaimed subject matter or has otherwise limited the scope of the claims." *Rexnord*, 274 F.3d at 1343. The court should also examine the prosecution history to determine whether the patentee has ascribed a special meaning to the term that is inconsistent with the term's ordinary meaning. *Vitronics*, 90 F.3d at 1582. Furthermore, any meaning that was disclaimed during the prosecution of the patent as revealed by the prosecution history is excluded. *Vitronics*, 90 F.3d at 1583.

The parties dispute the meaning of the language "greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone" as it is used in Claims 1 and 2 of the '252 patent.

The '252 patent claims:

> 1. A process for treating pain in a mammal which comprises administering to the mammal the amount of a pharmaceutical composition effective to provide an analgesic effect, said pharmaceutical composition comprising hydrocodone or a pharmaceutically acceptable acid addition salt thereof and ibuprofen or a pharmaceutically acceptable acid addition salt thereof, the ration of hydrocodone to ibuprofen being within the range that the administration of a therapeutic amount of said composition to a mammal will provide a greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone.

> 2. A pharmaceutical composition which comprises hydrocodone or a pharmaceutically acceptable acid addition salt thereof and ibuprofen or a pharmaceutically acceptable acid addition salt thereof in amounts that are sufficient to provide an analgesic effect, the ratio of hydrocodone to ibuprofen being within the range that the administration of a therapeutic amount of said composition will provide a greater analgesic effect than the effect obtainable by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone.

'252 Patent, Col. 5, ll. 12-34; Col. 6, ll. 1-3.

Plaintiffs argue that this language should be construed as "describ[ing] a composition consisting of hydrocodone and ibuprofen in a ratio sufficient to provide a 'greater analgesic effect' than the effect obtained by using either hydrocodone or ibuprofen alone" at the same dose. (Pls.' Mem. Supp. Mot. Summ. J. Patent Infringement at 7-8.) Plaintiffs argue that this is the proper construction of the terms because the language is unambiguous, and one of ordinary skill in the art would understand the terms "greater analgesic effect" to mean greater than the analgesic effect at the same dose.

Teva argues that the language in Claims 1 through 6 "indicates that the combination [of hydrocodone and ibuprofen] is to be compared against whatever therapeutic dose of hydrocodone alone and ibuprofen alone that provides the maximum analgesic effect." (Teva's Opp'n Pls.' Mot. Summ. J. Patent Infringement at 8.) Teva argues that because the specification states that the therapeutic dosage range in humans of ibuprofen is 200 to 400 mg and that of hydrocodone is 5 to 10 mg, the claim language should be construed to mean that "the combination [of hydrocodone and ibuprofen] outperform[s] the maximum therapeutic dose of ibuprofen alone (400 mg) and hydrocodone alone (10 mg), not merely ibuprofen or hydrocodone in the 'same dose' as in the combination." (*Id.* at 8-9.) This meaning is based on (1) the use of the claim term "obtainable",

which Teva argues indicates that the combination should be compared to the therapeutic doses of the drugs providing the maximum practical analgesic effect and (2) representations that Dr. Arnold made to the PTO, the EPO, and the Israeli Patent Office ("IPO") that the combination was novel because it provided a greater analgesic effect than either constituent at an increased dose.

"Obtainable" is defined as "capable of being obtained [;] available." Webster's Third International Dictionary 1559 (3d ed. 1986). This language, in Claims 1 and 2, does not suggest that the "greater analgesic effect" means that the claimed combination must outperform the maximum dosages of the component drugs in humans.

Neither the '252 patent's claims nor the specification contain any language that the terms "greater analgesic effect" have a plain meaning that would require the combination to outperform the component drugs at a maximum dose or any other increased dose. The plain language of the claims does not state that the combination provides a greater analgesic effect than the component drugs at an increased dose or a maximum dose. No dose or dose range is mentioned at all. Rather, Claims 1 and 2 clearly state that the combination provides a greater analgesic effect than either hydrocodone or ibuprofen alone.

Moreover, nothing in the claim language or the specification supports a construction that requires the claimed combination to provide a "greater analgesic effect" than a maximum dosage in humans. The plain language of the patent claims "a process for treating pain in a mammal which comprises administering to the mammal," '252 Patent, col. 5, ll. 12-13; "the ratio of hydrocodone to ibuprofen being within the range that the administration of a therapeutic amount . . . to a mammal will provide a greater analgesic effect," *Id.*, col. 5, ll. 18-21, 30-33. The use of the term "mammal" rather than "human" indicates that the "greater analgesic effect" of the claimed combination should

not be limited to human doses because humans are merely a subset of mammals. Moreover, in describing the preferred embodiment, the '252 patent states "the regimen will be prescribed by the physician or veterinarian[,] depending on the needs of the individual patient" which indicates that the patentee did not limit the claim terms by or to any human doses.

Furthermore, the prosecution history does not contain "any limiting definitional arguments or concessions that would require the [terms "alone" and "greater analgesic effect"] to be interpreted with the added requirements" Teva seeks to impose. *Burke, Inc. v. Bruno Independent Living Aids, Inc.*, 183 F.3d 1334, 1341 (Fed. Cir. 1999).

Therefore, based on the foregoing, a "greater analgesic effect" is construed to mean "a greater analgesic effect than the effect capable of being obtained by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone at the same dose."

Claims 3 through 6 do not use the "greater analgesic effect" term, and neither party appears to dispute the meaning of any terms in those claims. Thus, based on the plain language of the terms, the remaining claims are construed as follows.

Claim 3 is construed to claim "a process for treatment of pain in a mammal which comprises administration to the mammal one part by weight of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and about twenty to eighty parts by weight of ibuprofen or a pharmaceutically acceptable salt thereof."

Claim 4 is construed to claim "a pharmaceutical composition comprising a pharmaceutically acceptable carrier and an analgesically effective amount of (1) one part by weight of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and (2) about twenty to eighty parts by

weight of ibuprofen or a pharmaceutically acceptable salt thereof."

Claim 5 is construed to claim "a process for treating pain in a mammal which comprises the administration to the mammal of a dosage unit of (1) 5 to 10 mg of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and (2) 200 to 400 mg of ibuprofen or pharmaceutically acceptable acid addition salt thereof."

Claim 6 is construed to claim a "pharmaceutical composition in unit dosage form comprising a pharmaceutically acceptable carrier and (1) 5 to 10 mg of hydrocodone or a pharmaceutically acceptable acid addition salt thereof and (2) 200 to 400 mg of ibuprofen or a pharmaceutically acceptable salt thereof."

Invalidity

Teva argues that summary judgment on the issue of invalidity is appropriate because (1) the '252 patent claims are anticipated by the Upjohn Application and (2) the claimed invention was obvious to persons of ordinary skill in the art of pain management in 1984 when the '252 patent application was filed.

A patent is presumed valid. 35 U.S.C. § 282 (2002). A party challenging the validity of a patent must overcome the presumption of validity by clear and convincing evidence. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000). A patent is invalid if the claimed invention is "anticipated" or "obvious" in light of the prior art. *See* 35 U.S.C. §§ 102, 103 (2002).

A claimed invention is "anticipated", and thus not novel and not patentable, if, before invention by the patentee, it was known, used, sold, or described in a printed publication. 35 U.S.C. § 102. In an anticipation analysis, the claims are first construed. *Helifix*, 208 F.3d at 1346. Second, the court will compare the construed claim to the prior art. *Helifix*, 208 F. 3d at 1346. "To be

anticipating, a prior art reference must disclose 'each and every limitation of the claimed invention[,] . . . must be enabling[,] and [must] describe . . . [the] claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention.'" *Helifix*, 208 F.3d at 1346. The prior art reference must enable a person of ordinary skill in the art to make or obtain the claimed invention without an undue amount of experimentation. *Helifix*, 208 F.3d at 1348.

The claimed invention will produce a "greater analgesic effect than the effect capable of being obtained by use of either hydrocodone or a pharmaceutically acceptable acid addition salt thereof or ibuprofen or a pharmaceutically acceptable acid addition salt thereof alone at the same dose."

Teva argues that the Upjohn Application anticipates Claims 1 and 2 in that it discloses that an equi-analgesic dose of hydrocodone could be substituted for morphine sulfate and combined with ibuprofen to act synergistically to relieve moderate to severe pain. Teva further argues that persons of ordinary skill in the art in 1984 would have known that "acting synergistically" meant that the combined analgesic effect of the two drugs was greater than the effect of each drug given alone. Thus, Teva argues, the Upjohn Application discloses each and every limitation of the '252 patent.

Plaintiffs argue that the '252 patent was not anticipated by the Upjohn Application because the Upjohn Application does not identify the equi-analgesic doses of morphine sulfate and hydrocodone. Plaintiffs argue that a person of ordinary skill in the art in 1984 would only have been able to determine the equi-analgesic dose of hydrocodone after undue experimentation.

Both parties present affidavits by experts that purport to establish whether the person of ordinary skill in the art in 1984 would have known, or knew, how to calculate, the equi-analgesic dose of hydrocodone. Teva's expert states that the person of ordinary skill in the art in 1984 would

have known that certain specific oral doses of hydrocodone were equi-analgesic to oral doses of morphine sulfate. Plaintiffs' expert states that the person of ordinary skill in the art in 1984 would not have known the equi-analgesic oral dose of hydrocodone or how to calculate it.

As noted previously, the Upjohn Application does not disclose the specific equi-analgesic dose of hydrocodone. Furthermore, Teva's expert does not cite any prior art reference, other than his own averments, that indicates that persons of ordinary skill in the art knew the equi-analgesic dose of hydrocodone or how to calculate it.

Teva advances the same argument in stating that the Upjohn Application anticipates Claims 3 through 6. However, as noted above, the Upjohn Application does not indicate the equi-analgesic dose of hydrocodone that must be substituted for morphine sulfate, and the experts' assertions are not supported by any documentary evidence.

"An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself." *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997). Thus, summary judgment on the issue of anticipation is inappropriate because, based on plausible and detailed expert statements, there remains a genuine issue of material fact as to the knowledge of the person of ordinary skill in the art regarding the claim.

"A patent may not be obtained[,] though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the [relevant] art." 35 U.S.C. § 103.

Obviousness is a question of law resting on underlying factual inquiries. *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1284 (Fed. Cir. 2000). Those factual inquiries are (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) other secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Secondary considerations include commercial success, long felt but unsolved needs, and failure of others. *Graham*, 383 U.S. at 18. Once a party has set forth a *prima facie* case of obviousness, the patent owner may rebut the *prima facie* case with secondary considerations. *See Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000). Summary judgment is appropriate "only when the underlying factual inquiries present no lingering genuine issues." *Beckson Marine, Inc. v. NFM, Inc.*, 292 F.3d 718, 723 (Fed. Cir. 2002).

Teva argues that the '252 patent is invalid because it would have been obvious to combine the two component drugs of the claimed invention. Teva bases this argument on the drug Vicodin and the Beaver, Cooper, and Ferrer-Brechner articles, which all disclose or suggest the combination of a narcotic analgesic with an NSAID. Knoll argues that the evidence presented by Teva on this issue is more consistent with "obvious to try" than obviousness.

"Obvious to try" is not the standard under § 103. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Rather, for obviousness, there must be a reasonable expectation of success. *In re O'Farrell*, 853 F.2d at 903. A claimed invention is "obvious to try" if the prior art gives "no indication which parameters were critical or no direction as to which of many possible choices is likely to be successful" or gives "only general guidance as to the particular form of the claimed invention or how to achieve it." *In re O'Farrell*, 853 F.2d at 903.

The Federal Circuit Court of Appeals has held that a claimed invention (a combination of a

potassium conserving diuretic and a potassium excreting diuretic) was *obvious* and not "obvious to try" where the prior art expressly taught co-administration of a novel diuretic with other diuretics known to enhance the elimination of potassium and sodium ions because success was "not dependent upon random variation of numerous parameters." *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). Rather, the prior art "instruct[ed] the artisan that any of the 1200 [sic] disclosed combinations [would] produce a diuretic formulation with desirable sodium and potassium eliminating properties." *Merck*, 804 F.2d at 807. The claimed invention was still obvious even though the prior art disclosed 1,200 possible combinations because "the claimed composition [was] used for the identical purpose taught by the prior art." *Merck*, 804 F.2d at 807.

Here, the prior art expressly teaches the combination of a narcotic analgesic with an NSAID, the invention claimed in the '252 patent. As was noted above, Vicodin is a combination of hydrocodone and acetaminophen. The 1981 Beaver article documented that a greater analgesic effect could be achieved through the combination of a narcotic analgesic and a peripherally acting non-narcotic analgesic, such as aspirin or acetaminophen. The 1984 article by Beaver suggested the substitution of ibuprofen for the acetaminophen in Vicodin because they share the same mechanism of action. The Beaver article also stated that ibuprofen could be "used to advantage in combination with oral opioids." The Beaver article did not disclose which opioid should be combined with which NSAID or the specific ratios and dosage amounts. The Cooper article disclosed a combination of codeine and ibuprofen. The Ferrer-Brechner article disclosed a combination of methadone and ibuprofen. Here, success was dependent not upon random variation of numerous parameters but rather on combining an opioid with an NSAID to produce a pain reliever with a greater analgesic effect. The prior art expressly teaches one of ordinary skill in the art to combine an opioid with an

NSAID. Furthermore, based on the prior art, a person of ordinary skill in the art of pain management would have had a reasonable expectation of success in combining hydrocodone, a narcotic analgesic, with ibuprofen, an NSAID. *See In re O'Farrell*, 853 F.2d at 903. Thus, there is clear and convincing evidence that the combination of hydrocodone and ibuprofen was obvious and, therefore, unpatentable. *See* § 103.

Moreover, secondary considerations do not rebut Teva's *prima facie* case of obviousness. Others had not tried and failed to create a opioid-NSAID analgesic combination. Rather, the evidence presented shows that, in 1984, others had successfully created and marketed to consumers opioid-NSAID analgesic combinations, e.g. codeine-aspirin, codeine-acetaminophen, hydrocodone-acetaminophen, oxycodone-acetaminophen, oxycodone-aspirin, propxyphene-acetaminophen, and propoxyphen-aspirin. (*See* Def.'s 56.1 Ex. 28 at 789, 791, 835, 921, 927, 1009, 1121.)

"One way for a patent [owner] to rebut a prima facie [sic] case of obviousness is to make a showing of 'unexpected results,' i.e. to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Plaintiffs identify three investigations in which scientists discovered that the claimed invention had unexpected benefits from "(1) a synergistic relationship between hydrocodone and ibuprofen when these two drugs are combined in the ratio and dosage amounts specified in the ['252 patent] . . . and (2) [the claimed invention's] unexpected ability to enhance anaerobic performance following exercise-induced muscle damage." (Pls.' Mem. Opp'n Def.'s Mot. Summ. J. at 34.) However, these unexpected benefits or results were discovered after the '252 patent had been issued. Plaintiffs have not identified any authority that unexpected results discovered long after the issuance of a patent may be properly considered on the

issue of obviousness. Furthermore, it is clear that, in 1984, Plaintiffs were unaware of these unexpected results.

Another secondary consideration is the skepticism of others and whether the prior art teaches away from the claimed invention. *See Monarch Knitting Mach. Corp. v. Sulzer Morat GMBH*, 139 F.3d 877, 885 (Fed. Cir. 1998). "A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant.'" *Monarch Knitting Mach. Corp.*, 139 F.3d at 885 (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). Here, the prior art references clearly teach the combination of an opioid and an NSAID. Moreover, the Beaver article even suggests the substitution of ibuprofen for the acetaminophen in Vicodin, which would result in the combination claimed in the '252 patent.

Finally, Plaintiffs' evidence of commercial success does not raise any genuine issue of material fact as to whether the '252 patent is obvious. The patent owner must show a nexus between the merits of the claimed invention and its commercial success. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991). "[P]rima facie [sic] evidence of nexus is established if there was commercial success and if the invention disclosed in the patent was that which was commercially successful." *Ryko Mfg. Co.*, 950 F.2d at 719. Even assuming that there is the required nexus, the sales of Plaintiffs' hydrocodone-ibuprofen product are of insufficient weight to overcome this Court's determination of obviousness based on consideration of the prior art, the lack of differences between the claimed invention and the prior art, and the level of ordinary skill in the art. *See Ryko Mfg. Co.*, 950 F.2d at 719. Therefore, Teva's motion for summary judgment of invalidity is granted on the ground of obviousness.

Because the Court finds that the '252 patent is invalid, it need not reach the issue of whether Teva has infringed the '252 patent.

CONCLUSION

For the reasons stated herein, Teva's motion for summary judgment of patent invalidity is granted. Teva's motion for summary judgment of non-infringement and Plaintiffs' motion for summary judgment of infringement are denied moot.

IT IS SO ORDERED.

John W. Darrah, Judge
United States District Court

Date: September 12, 2002